K083503

FEB 1 8 2009

Toshiba America Medical Systems, Inc.
510(k) Pre-market Notification; DRAD-3000E, RADREX-i

510(k) Summary

Date:	November 21, 2008
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	DRAD-3000E, RADREX-I, with TFP-4336A portable detector
Common Name:	Solid State X-ray Imager (Flat Panel/Digital Imager) [Fed. Reg. No. 892.1650, Pro. Code: 90MQB/KPR]
Regulatory Class:	II (per 21 CFR 892.1650)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s):	Toshiba DRAD-3000E, RADREX-i [k082494] Philips Medical Systems Bucky Vision (Digital Diagnost) 510(k) Control Number: K982795
Reason For Submission	Modification to existing device

Description of this Device:
The RADREX-I is a general purpose x-ray system that employs Solid State Imager(s), SSXI, which converts x-rays directly into electrical signals which can, after appropriate processing be displayed on LCD monitors or printed to a medical grade image printer. The system console is a PC based device that allows for worklist management, image storage, image processing, image exporting and image printing. The system may be equipped with a table and/or vertical wall unit, is configurable with up to two x-ray tubes, and has an optional auto stitching function.

Summary of Intended Uses:
This system is intended for use in conjunction with the ceiling-suspeneded tube support, high voltage generator, and bucky stand or bucky table incorporating a fixed or detachable (portable) flat panel detector for radiography of the head, chest, abdomen, spine, neck and limbs. This

system is used for image acquisition, image display and transmission/output or images to external devices. Excluded indications include mammography, fluoroscopy and angiography studies.

Technological Characteristics:
This device employs similar materials and processes as found in the predicate devices. The device produces ionizing radiation that is employed to generate radiographic images of the anatomy.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020, that apply to this device, will be met and reported via an initial report. Additionally this system is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60601-2-32, and IEC 60601-2-28. - Medical Device Safety standards.

Substantial Equivalence:
The RADREX-I is of comparable type and substantially equivalent to:

Philips Digital Diagnost; [k982795]
Toshiba DRAD-3000E, RADREX-i [k082494]

Therefore the RADREX-I complies with the same or equivalent standards and has the same intended use as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Reviewer and Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG - 9 2013

Re: K083503
Trade/Device Name: DRAD-3000E; RADREX-I with TFP-4336A portable detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: February 2, 2009
Received: February 3, 2009

Dear Mr. Job:

This letter corrects our substantially equivalent letter of February 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083503

Device Name: DRAD-3000E; RADREX-i with TFP-4336A portable detector

Indications for Use:

This system is intended for use in conjunction with the ceiling-suspended tube support, high voltage generator, and bucky stand (fixed detector only) or bucky table incorporating a fixed or detachable (portable) flat panel detector for radiography of the head, chest, abdomen, spine, neck and limbs. This system is used for image acquisition, image display and transmission/output or images to external devices. Excluded indications include mammography, fluoroscopy and angiography studies.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083503